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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
|-----------------|-------------|----------------------|---------------------|------------------|

10/567,918

11/13/2006

Peter Gilbert Wiles

DAIRY88.017APC

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09/23/2009

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EXAMINER

PRATT, HELEN F

ART UNIT

PAPER NUMBER

1794

NOTIFICATION DATE

DELIVERY MODE

09/23/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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| | | | |
|------------------------------|--------------------------------------|-------------------------------------|--|
| Office Action Summary | Application No. 10/567,918 | Applicant(s) WILES ET AL. | |
| | Examiner Helen F. Pratt | Art Unit 1794 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 June 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 and 37-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-35 and 37-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 February 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5-12-06, 6-3-08</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 3 , 4, 10 13, 17, 37, 38 and 39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is not known when the process of claims 3 and 4 occur in step a. It is not known where the serum of claim 4 comes from. In claims 10 and 13, it is not known when these steps occur. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claims 17, 37 and 38 recite the

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broad recitation “more preferably”, and the claim also recites “more preferably” again which is the narrower statement of the range/limitation.

In claim 39 it is not known what ‘other portion’ refers to.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-35, 37- 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kumazawa et al (20020043159) in view of Swanson et al. (4,343,817) and Brody (2003/0166866).

Kumazawa et al. disclose a process of making an enhanced the yield of cheese by separating a cheese curd from the whey after a coagulating treatment, adding a

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protein decomposing enzyme to the whey protein to make a partial hydrolysate and adding this to the material milk allowing transglutaminase to act on the mixture, coagulating the milk mixture with an enzyme to make a cheese curd (abstract). Claim 1 differs from the reference in the step of dissolving the protein concentrate in a salt solution to form a liquid and blending the liquid with the serum to form a protein composition. The reference to Swanson et al. disclose combining dry calcium with calcium hydroxide to make a calcium caseinate (col. 3, lines 14-20, 29-59). It is assumed that there is liquid with the calcium hydroxide in order for the reaction to go forward. Therefore, it would have been obvious to dissolve the protein concentrate in a liquid salt mixture in the process of Kumazawa et al. for the function of combining protein concentrate (casein) with whey. (It is noted the this rejection is made using the Summary of the invention on page 3 of the specification as the claims are so involved, and seeming to contain 3 variations that they are hard to address).

The dairy stream can be skim milk (0006) and can be pasteurized (0049 Kumazawa et al.).

Membrane concentration using ultrafiltration is a well known procedure in the cheese and milk area (claim 7) of Kumazawa et al. Para 0010 discloses concentration of whey and material milk by ultrafiltration.

Adjusting the pH of a first portion to 4.5 to 4.8 is seen as being within the skill of the ordinary worker, and then reacting a portion of the dairy stream with an enzyme to make para-kappa casein is disclosed in 0006 of Kumazawa et al. Step 1 (b) iii of combining the portions then heating to form a protein concentrate and serum is

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disclosed by Kumazawa et al. who add milk whey protein to material and subjects such to a coagulating treatment to make a cheese curd (abstract). Heat treating is a coagulating treatment which would have made a protein concentrate and a serum, as the mixture coagulates at that temperature, and whey is released.

It is notoriously old to use an acid to adjust the pH of milk and certainly to use food safe acids such as hydrochloric or sulphuric acids.

Acidification using a starter culture is also the way cheese is made as on page 4 of the spec, first paragraph), and then adjusting the pH to 4.6 to effect coagulation is notoriously known.

Paragraph 3, on page 4 further requires using an enzyme on kappa casein at very low temperatures. However, it would have been within the skill of the ordinary worker to use temperatures at which the enzymes will react, as this is just a case of adjusting the temperatures absent a showing to the contrary.

Chymosin is a well known enzyme which is the same as rennin. Combining the dairy streams and heating at fairly low temperatures is seen as being within the skill of the ordinary worker since one must consider not deactivating the enzyme, but causing coagulation, which can make a protein concentrate from the heated dairy stream.

Washing the protein concentrate with water, and adjusting the pH and milling are well known procedures with an obvious outcome. Mixing the protein concentrate in an alkaline salt solution has been disclosed above and the particular amount of monovalent cations is seen as being within the skill of the ordinary worker depending on the amount of alkalinity required.

Adjusting the protein levels by adding more protein is seen as being within the skill of the ordinary worker. Concentration of the serum into a protein rich stream is disclosed by Kumazawa et al. (0010). Kumazawa et al. disclose that it is known to remove excessive lactose (0007) and Brody disclose that the permeate contains lactose and minerals produced by UF (0053). Therefore, it would have been obvious remove lactose from a milk stream.

Combining the various products from ultra-filtrating milk is seen as being within the skill of the ordinary worker as the reference to Brody discloses that whey protein concentrate with fat, water lactose or reduced amounts of each and such can be combined with dairy material, such as skim milk (0066 and 0067). Therefore, it would have been obvious to combine various protein concentrates to make combined milk products.

Certainly, nothing new is seen in homogenization, or using a multistate evaporation equipment or drying a product by spray drying as these processes are used often when making cheese.

Therefore, it would have been obvious to use the method of Brody in the process of Kumazawa et al. to make a protein composition from a dairy stream.

The composition as in claim 33 has been shown by the combined references as in claim 33, and would have had high concentrations of calcium since the milks are concentrated. The sodium concentration could also have been adjusted to a reasonable amount since this only amounts to adding salt, or ultra-filtering to that amount as in claim 34.

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A powdered product is disclosed by Brody et al. in 01701. Therefore, it would have been obvious to powder to composition of the combined references as in claim 35.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Helen F. Pratt whose telephone number is 571-272-1404. The examiner can normally be reached on Monday to Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Milton Cano, can be reached on 571-272-1398. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Helen F. Pratt/

Primary Examiner, Art Unit 1794

Hp 9-18-09